



AUG 1 2011

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901 New York Ave., NW
Washington, DC 20001-4413

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,925,730

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,925,730, claims of which cover the human drug product FIRMAGON® (degarelix acetate) and methods of using FIRMAGON® (degarelix acetate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,498 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,498 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 1, 2010 (75 Fed. Reg. 9227). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2} (\text{TP} - \text{PGTP})^1 \\ &= 2,695 - 0 - 0 - \frac{1}{2} (2,394 - 0) \\ &= 1,498 \text{ (4.1 years)}\end{aligned}$$

Since the regulatory review period began August 10, 2001, after the patent issued (July 20, 1999), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

¹ Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of $\frac{1}{2} (\text{TP} - \text{PGTP})$.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

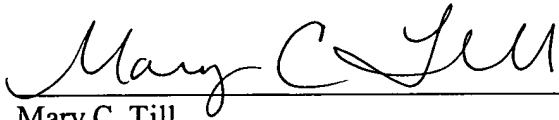
U.S. Patent No.:	5,925,730
Granted:	July 20, 1999
Original Expiration Date ² :	April 11, 2017
Applicant:	Graeme Semple et al.
Owner of Record:	Ferring BV
Title:	GNRH Antagonists
Product Trade Name:	FIRMAGON® (degarelix acetate)
Term Extended:	1,498 days
Expiration Date of Extension:	May 18, 2021

²Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy RE: FIRMAGON® (degarelix
 Food and Drug Administration acetate)
 10903 New Hampshire Ave., Bldg. 51, Rm. 6222 Docket No.: FDA-2009-E-0206
 Silver Spring, MD 20993-0002

Attention: Beverly Friedman